

**What value can qualitative research add to quantitative research design? An example from an adolescent idiopathic scoliosis trial feasibility study**

Qualitative research can make a useful contribution to the design of clinical trials. It can allow trial researchers to understand participants better and help to make sure that money is not wasted on trials that might otherwise fail. It can also help trial researchers to understand the successes and failures of trial interventions. However, only an estimated 3-18% of trials incorporate qualitative research (O'Cathain et al., 2014), although this estimate may be higher for trials of complex interventions (Lewin, Glenton, & Oxman, 2009). A recent systematic review (O'Cathain, Thomas, Drabble, Rudolph, & Hewison, 2013; O'Cathain et al., 2014) identified 296 trials reporting embedded qualitative research (2008 to 2010) that aimed to enhance trial design (2008 to 2010). O'Cathain and colleagues review the diversity of aims in qualitative research embedded in trials (O'Cathain et al., 2013; O'Cathain et al., 2014). They found studies that explored the content or delivery of the trial intervention, trial feasibility, acceptability of interventions, design and conduct of the trial and the appropriateness of the outcomes measures. A smaller number of studies explored the specific health condition in order to contextualise trial findings. Their study highlights variability of aims in qualitative research embedded in trials. Their work is supported by another systematic evaluation of 30 qualitative studies embedded in one hundred trials of complex interventions (Lewin et al., 2009).

Despite the reported benefits of qualitative research alongside trials, are we making the most out of this qualitative research embedded in quantitative research design?

Firstly, not all of the qualitative studies are published; for example only 19 of the 30 studies evaluated by Lewin and colleagues (Lewin et al., 2009). Secondly, when published, the specific value of findings are not always clearly articulated (O'Cathain et al., 2013), making it difficult to utilise the knowledge. Finally, there are *epistemological* differences between qualitative research and clinical trial methodology that can make it difficult to evaluate the utility of qualitative findings embedded in trials. Epistemology concerns how we determine what things are true; for example, how does a proposition become a fact; when does belief become knowledge? For researchers this is important because it underpins the research methods that we choose to determine whether something is *true* or valid. Specific research traditions have accepted methods for determining what is *true*. In contrast to trials (and other quantitative) methodology, qualitative research is underpinned by an interpretive

framework, which sees knowledge as a dialectic *process* taking place in the space between individuals, each with a unique a priori world-views (or 'bias'). Qualitative methods are concerned with providing alternative interpretations that encourage us to challenge our a priori views. For quantitative trial researchers, knowledge is constructed as *factual* and energy goes into systematically removing *bias* in order to discover solid facts. These two genres of knowledge, each with their own value, resonate with Aristotle's descriptions of *phronesis* (experiential wisdom) and *episteme* (factual knowledge) (Frank, 2004). Another difference is that qualitative research aims to generate ideas that are grounded in empirical data (*inductive epistemology*), whereas trials are designed to test out ideas in a controlled setting (*deductive epistemology*). These epistemological differences underpin unique research aims and methods.

Using one example of a qualitative research study set alongside a trial feasibility study, we explore the benefits of including qualitative research in trial design, and reflect on some of the epistemological challenges. The qualitative study was part of a project that evaluated the feasibility of conducting a randomised controlled trial (RCT) of specific exercises for young people with adolescent idiopathic scoliosis (Williams et al., 2015). Adolescent idiopathic scoliosis (AIS) is a three dimensional spinal deformity that results in lateral deviation, rotation and flexion/extension of the vertebrae. It is of unknown cause and occurs at or near the onset of puberty. The aim of the exercise programme was to reduce progression or improve the curvature of their spine. The prevalence of AIS in children aged 10-16 years is 1-3% (Kesling & Reinker, 1997; Parent, Newton, & Wenger, 2005) and current UK management includes monitoring, bracing for some and, for the most progressive and serious cases, surgery. An estimated 90% of AIS cases do not require surgical or bracing and exercise has been proposed as a promising non-surgical intervention (Fusco et al., 2011; Negrini et al., 2008). We searched bibliographic databases to identify any qualitative research exploring the experience of AIS (Medline, Psychinfo, EMBASE, Cinahl). Figure 1 gives an example of the Medline search syntax used to identify studies. Identified studies focused on the experience of surgery and bracing (Bull & Grogan, 2010; R. Macculloch et al., 2009; R. Macculloch, J. Nyhof-Young, D. Nicholas, S. Donaldson, & J. G. Wright, 2010; Sapountzi-Krepia et al., 2006). Sapountzi-Krepia and colleagues (Sapountzi-Krepia et al., 2006) explored the experience of bracing and found that participants with AIS reported having to deal with stress, denial, fear, anger, and shame. Rullander and colleagues (Rullander, Isberg, Karling, Jonsson, & Lindh, 2013) also described the emotional aspects of

undergoing surgery, including fear, nightmares, nervousness, and helplessness, both before, during and after surgery. Macculloch (R. Macculloch, J. Nyhof-Young, D. Nicholas, S. Donaldson, & G. Wright, 2010) explores the perspective of both healthcare providers and AIS patients, in order to more fully understand the information needs of adolescents undergoing surgery (Radha Macculloch et al., 2009). Finally, Donnelly and colleagues explore the complexity of decision making of parents and adolescents when considering treatment (Donnelly, Dolan, Grande, & Weinstein, 2004). Our review demonstrates the paucity of qualitative exploration in AIS and identified no existing research exploring the experience of living with AIS or exercise rehabilitation.

The aims of the qualitative study were to explore the feasibility of the trial, including trial recruitment and acceptability of the intervention, participants' perception of the trial intervention, any issues influencing exercise adherence, and the appropriateness of the chosen trial outcomes.

**Method**

*Ethics* - Approval to conduct this study was granted by the East of England – Cambridge South Research Ethics Committee (reference no. 12/EE/0331).

**Study context**

The qualitative study was embedded in multi-component feasibility study which included a UK clinician survey, systematic literature review and a pilot randomised controlled trial. The aim was to assess the feasibility of a large, multi-centre trial of scoliosis specific exercise treatment for patients with AIS, in comparison to standard care. Fifty adolescents were randomised across four secondary care UK National Health Service (NHS) trusts providing specialist care for patients with AIS. The trial recruited people aged 10-16 years with mild to moderate AIS defined as a Cobb angle between 10 and 50 degrees on x-ray. Although these were under the care of an orthopaedic surgeon they were unlikely to be eligible for surgery. Participants were either allocated to standard care (advice and education) or a physiotherapy scoliosis-specific exercise programme supported by a home exercise plan. Our choice of intervention was informed by a systematic review of exercise interventions for AIS. We involved clinicians in the design of the interventions through an intervention development day. There was no previous qualitative research to draw on in this specific area and a he qualitative study would allow us to explore in detail the participants' experience of

the trial. This could not have been done using quantitative methods or from other literature.

The exercise intervention involved between 6 to 9 appointments with a physiotherapist spread over 6 months. The aim of the exercise programme was to teach the participant to correct their posture and then maintain the corrected position. Each participant was assessed and given an individualised exercise programme based on the presenting spinal deformity. The first step of the exercise programme was to teach the participant to correct their posture. Participants were also given additional exercises that progressively challenged their ability to maintain the corrected posture by altering position, adding load or resistance, adding movement or distractions and incorporating it into activities of daily living. Exercises to address any secondary impairments (e.g. balance, range of movement, strength) were also included if indicated. Alongside the exercise programme the physiotherapist provided education, advice and support for the participant and family. Participants were asked to perform the exercises daily and completed an online exercise diary to help them adhere to the exercises and allow their physiotherapist to monitor progress. The main outcome was feasibility of recruitment to the randomised study. Other elements were to inform choice of outcomes for a definitive trial. The randomised study recruited 58 patients from four NHS trusts over 11 months.

### **Data collection**

At initial recruitment to the pilot RCT, young people and their parents were asked for consent for the research team to contact them regarding the qualitative study. We chose not to interview patients or their parents at the trial outset as some had just been informed of their diagnosis and we felt that this might cause undue distress. As part of the on-going process of obtaining consent, at the last treatment session the treating physiotherapist asked if the family were still happy to be contacted about taking part in an interview. If so, they were then provided with an information leaflet and their contact details were passed onto the qualitative research team. Participants were given at least 48 hours to read the information sheet, and had the opportunity to contact the study team with any further questions. The research team then contacted the parent to establish if the family wished to participate and, if appropriate, arranged a suitable time and venue to meet with the family for interview. At this meeting, Fran Toye discussed the interviews further and answered any questions. She was then responsible for obtaining consent from the young person and their parent if they agree to take part in an interview. Consent was be obtained separately for each interview (adolescent and parent).

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We followed the MRC guidance on seeking consent from children to participate in research (Medical-Research-Council, 2004). Where a child was assessed as having capacity to consent to take part in the study we sought his or her consent. In addition, we sought agreement from parents to allow their children to participate. Where a child was judged not to have capacity to consent to participate, consent was obtained from his or her parent, provided agreement was also obtained from the child. Thus for all participants we had agreement (either consent or assent) from both the child and the parent. Researchers responsible for obtaining consent were provided with training in seeking consent from children and assessing capacity to consent. We developed three versions of information leaflet to provide potential participants and parents with information about the possible risks and benefits of taking part, one for younger children unlikely to have capacity to consent, one for older children likely to have capacity to consent and one for parents. All three information leaflets were provided as a pack to ensure patients and their parents had a choice of materials to read. They were developed with the help of patients and parents.

We developed an interview schedule (Figure 2) in collaboration with relevant stakeholders (children, parents, health care professionals). However, the schedule was used as a guide and interviews remained semi-structured to allow the flexibility to follow leads opened by participants. This is a useful approach in research where the aim is to explore personal meanings. Participants were given the choice to be interviewed at hospital or in their own home. They were encouraged to discuss any area they felt was relevant to their experience of the trial. Kirk emphasises the importance of making children feel an important part of the research, to talk to and interview children with respect and empathy, to ensure that interviewers are aware of non-verbal cues that children may use to indicate they wish to terminate an interview and inviting children to comment on their transcript (Kirk, 2007). We adopted this guidance. The physiotherapists delivering the treatments were also invited to take part in an interview after they had delivered the exercise intervention for at least two participants.

Fran Toye conducted 16 interviews in total (6 interviews with girls taking part in the exercise intervention, 4 interviews with their mothers, 2 interviews with both mother and father, 2 with physiotherapists experienced in providing exercise interventions for patients with AIS and 2 with physiotherapists with limited experience). The six girls were aged between 10-16 years, three had significant pain before the trial. All the girls were white, and were similar in terms of sexual maturity, disability and self-image (as indicated by standardised outcome

measures). Interviewees were of similar age to the trial participants but none of the five boys allocated to the exercise intervention agreed to be interviewed. All parent participants were parents of the adolescent participants.

Interview duration ranged from 35 minutes to 2 hours with physiotherapists; 50 minutes to 1 hour 50 minutes with parents and 40 minutes to one hour 10 minutes with adolescents. We interviewed to a point where we found useful themes to support the trial aims, and which was consistent with the feasibility trial design. The sample included 10% of the trial participants and is consistent with qualitative epistemology (Smith, Flowers, & Larkin, 2009).

Interviews were digitally recorded and transcribed verbatim. To assist analysis, Fran Toye loaded each transcript onto Nvivo 9 software (Nvivo, 2010). Fran Toye is an anthropologist and qualified physiotherapist who has undergone surgery for AIS. Although an experienced qualitative researcher, this was her first experience of qualitative research within a trial feasibility study and this allowed her to make comparisons between stand-alone and embedded qualitative research projects. Fran Toye was part of the trial feasibility team. Three of the co-authors (Esther Williamson, Mark Williams, and Sarah Lamb) are physiotherapists and researchers; one co-author Jeremy Fairbank is an experienced spinal surgeon and researcher. All had extensive trial experience in surgical and/or rehabilitation trials. Esther Williamson has undertaken qualitative studies alongside large randomised controlled trials. Patient and public representatives were involved throughout this study. Links with patients and the public were made via the national patient charity Scoliosis Association UK (SAUK), via consultant spinal clinics and through informal individual contact. Prior to commencing the full qualitative study, a young person and their parents were consulted and their feedback received on the interview schedule, the consent process and the opportunity to interview patients and parents separately. A pilot interview was conducted with this family. They also reviewed the questionnaires to be used in the study. A representative from SAUK sat on the Independent Monitoring Committee.

*Analysis* - We used the methods of Interpretive Phenomenological Analysis to interpret the interview data (Smith et al., 2009). We used constant comparative methods to abstract useful ideas. This involves an iterative process of constantly comparing data, codes and categories within and across cases, and moving from an initial tentative category towards progressively abstracted theoretical categories that are grounded in the data. Our approach

to research quality is outlined by Toye and colleagues (Toye et al., 2013). Fran Toye, Esther Williamson, Sarah Lamb, Mark Williams and Jeremy Fairbank collaboratively challenged analytic decisions from the coding process in regular research team meetings. The aim of this collaborative process is not to reach consensus about ideas but to develop ideas dialectically. Central to dialectic theory is the idea that tension between different ideas can create innovative ways of thinking (Forster, 1993). Within this dialectic framework, *knowing* can be conceptualised as a dynamic process that occurs at the *interface*. We have also utilised narrative exemplars to allow the reader to judge our analytical decision making. The focus of collaboration at team meetings was to identify ideas that would influence the design of a full trial.

**Findings**

We aimed to explore the feasibility of the trial, including trial recruitment and acceptability of the intervention, participants’ perception of the trial intervention, any issues influencing exercise adherence, and the appropriateness of the chosen outcomes. Our findings are organised into the following areas: (1) the conduct of trials and acceptability of the trial intervention; (2) the valued outcomes and trial outcomes; (3) the experience of the disease condition.

**The conduct of trials and acceptability of trial intervention**

***It’s difficult to try and fit it in around school***

All participants describe the difficulty of fitting the intervention appointments around an active school life.

GIRL: [I have missed] about a week of school maybe out of all of it . . . and also just in making physio appointments . . . because if I am in school all day . . . [the hospital] opens at 9 and close at 4 . . . and they are not open at the weekends so it’s quite hard to try to make appointments in term, and also fit it around school and things like that

GIRL: I think it was just explaining . . . I can’t miss school . . . around [exams] . . . if you are younger it’s not that big of a deal but when it comes to that kind of thing you can’t be missing lessons really.

MOTHER: That is a bit stiff if you have got an appointment . . . and you do have to miss school, but you were doing your [school exams] . . . because you were part of the research stuff and in a more voluntary capacity . . . and I think that that message hadn’t got through [to hospital staff].

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PHYSIO: a very large percentage are likely to be doing [important school exams] so everything that eats into their time becomes a problem . . . I think people agree to be part of something that they really want to be part of but don't always think about all the problem areas before they agree.

***It's can be difficult to randomise a person to the non-intervention arm***

Physiotherapists described the difficulty of having to deal with the disappointment of families who had 'pinned their hopes' on being allocated to the intervention group.

PHYSIO: It sort of puts a dampener on the whole session really because they then don't really want to be here because they wanted something different . . . they don't necessarily feel like they've gained a lot from driving an hour and a half to get here.

Some physiotherapists were concerned that there might be patients who would benefit from exercises who would be allocated to the non-intervention group. They described how the person was a *patient* prior to being a research *subject*.

PHYSIO: If a patient is coming into a trial in the context of a referral to physiotherapy [as a patient], the physiotherapist has a duty of care . . . If I had someone presented to me in the advice [non-intervention] group, and in my opinion that patient has a right to [and will benefit from] physiotherapy, that patient should be pulled out of the trial.

**Trial outcomes - what is a good outcome?**

Findings included themes related to establishing the outcome of treatment: (a) it won't necessarily change the bony bits; (b) I didn't realise I stood like that; (c) she doesn't mention the pain now; (d) it gives her a sense of control; (e) creating a space for concerns; (f) talk to her like a person.

**It won't necessarily change the bony bits**

Although the girls and their parents felt that the intervention would not necessarily improve the 'bony' spinal curvature, other factors such as 'stopping [the curve] getting worse'



(mother), slowing down progression of curve, improving posture were considered important to them.

Fran Toye: did you think the exercises would have any impact?

GIRL: I think it was mainly my posture . . . I don't think it's helped my actual curve but I knew that it wasn't going to but it's helped me a lot with my posture.

GIRL: . . . well hopefully just to learn more about my scoliosis and also if it could slow it down or make some kind of improvement, realign myself more that would be good . . . I think the goals were just to maybe just to slow down the curvature and just help with getting my body more in line

MOTHER: No, not on her bones, on the degrees . . . on her spine. I knew it would be purely muscular and posture . . . I think knowing that it couldn't *cure* . . . but *help* her.

Physiotherapists also recognised that valued aspects of care should go beyond biomedical markers.

PHYSIO: I think if you can stop the curve getting worse and improve self-image, self-confidence, pain and core strength I think that's all positive.

However, they recognised that 'bony' outcomes often took precedence and this meant that other valued aspects of care, such as improving self-esteem, could be ignored. They also recognised that although a child, their parent, physiotherapist or surgeon might define a good outcome differently, all would consider curve progression to be a poor outcome.

PHYSIO: Treatment should be more focused on what the patient wants to achieve . . . but if . . . [the curve is] progressing then it's slightly different . . . they might say 'I'm not bothered by it' but the reality [is that] the curve is getting worse and it's *not* a good outcome. It's a tricky one.

### **I didn't realise that I stood like that**

Irrespective of bony changes, awareness of body posture and the ability to consciously alter posture was described as a valued outcome by the girls and parents.

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3 GIRL: I think I have a much better understanding of my curve and how it affects me.  
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5 I didn't actually realise that I had it . . . I didn't really realise how kind of like I stood  
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7 because before I had the physio; it was more like one of my hips jutted out more.  
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9 But then after physio . . . I think that's awareness of my posture how I sit and how  
10 that affects my back more  
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13 GIRL: I think the whole giving me more awareness, we had quite a lot of work where  
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15 we which taught me like a new position to stand in and like looking in the mirror and  
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17 seeing my curve and how it affected my body. I thought that was helpful because  
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19 now I just stand in that position like normally which is a big improvement.  
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22 MOTHER: She knows that if she doesn't want her shoulder to be lower than the  
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24 other . . . she can correct that herself slightly. She had her prom earlier this year and  
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26 she was having photographs taken for that so she would have corrected herself so  
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28 that her shoulders were even for the photos.  
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31 Physiotherapists also described the positive effect that postural control might have on self-  
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33 confidence.  
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36 PHYSIO: She was just really, really pleased with it and she actually went out in a vest  
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38 top last week. For me that was really lovely.  
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41 One of the physiotherapist described *unconscious*, habitual and dynamic postural change as  
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43 the only true measure of good outcome (although recognised that this could be difficult to  
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45 measure).  
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48 PHYSIO: The ability to hold themselves . . . in a more aligned way *unthinkingly* . . .  
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50 that is . . . the proof of it, is that it becomes a positive habitual change. Conscious  
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52 change is irrelevant.  
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#### 54 **She doesn't mention the pain anymore**

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56 Three of the girls suffered with back pain:  
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GIRL: It sometimes frustrates me that I am always in a lot of pain . . . it can be pretty depressing . . . I can't stand up for too long, always having to change positions always lying forward or back . . . having to straighten myself.

The girls, parents and physiotherapists noticed an improvement in pain, suggesting that pain is a modifiable outcome.

GIRL: There probably is a difference like when I was first doing the exercises, if I stop doing them then I am in a lot more pain and then I will start doing them again . . . when I am not doing them I am getting a lot of pain.

MOTHER: I noticed a big improvement that she doesn't get the pain anymore, she was complaining about it every day and I've really noticed she hasn't mentioned it.

Although physiotherapists did not describe pain as a feature associated with AIS, and that pain was not necessarily a target of treatment, some acknowledged that exercise had a positive impact on pain:

PHYSIO: there are one or two of them in the trial that definitely had very high levels of pain as much as 7 or 8 on the scale when they arrived and will say now that they don't have any pain and the parents will certainly say they don't talk about it now, they don't

**Doing something gives a sense of control**

All participants described the value of gaining a sense of control; of doing 'something positive', rather than waiting passively for an unknown outcome. Girls and their parents described how they 'would have been gutted' (mother) if they had been allocated to the non-intervention group because they needed to feel like they had a 'chance of something changing' (girl). Some described how, if they had not been allocated to the intervention, they would have sought alternative therapies (e.g. Yoga or Pilates) or get a second opinion. One mother was so disappointed that she contacted the referring consultant for another physiotherapy referral.

MOTHER: not because we doubted his opinion but because we *wanted to do something*. . . . If you sit back and do nothing then you don't know.

Girl: I wouldn't have liked [the non-exercise group] . . . if I just *spoke* to a person about it I don't think that would have helped me a lot. . . . I didn't know what the other one was. I just knew there was an intense one, and I got put in that one, so I didn't really get told what you would do in the other one.

Fran Toye: do you think you would have been involved in the trial?

Girl: I don't think I would have. Cos I don't think I would think it was helping me. Because I wouldn't be given exercises for specific things to help. So I don't think it would be useful to me. I would be a bit, I wouldn't say like annoyed but I would be a bit disappointed as I would prefer to be in [the exercise group], you have more of a chance of something changing . . . but obviously it's a question of funding

One father described the experience of being in the trial as a 'growth point', emphasising the value of '*doing something*'.

FATHER: She has seen herself in a different role; she has got satisfaction from feeling . . . she has contributed to something that will be helpful . . . you could call it an educational experience. I am not saying that I would want my daughters to have this . . . but 'how have I personally coped with this?' - When living, what you make of things and the choices you make . . . shape what you become. It has been an education.

### **The experience of the disease condition**

Our findings also revealed important themes related to the experience of AIS that are relevant to providing high quality care that are not necessarily related to the trial.

### **Creating a space for concerns**

This theme highlights an unmet information need, and the importance of creating families a space for concerns. Parents experienced shock and worry about not knowing the future and a sense of loss.

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MOTHER: I made the mistake of googling on the internet and it was the worst thing I could have done . . . I would advise anyone else not to do it because you see the most extreme cases and I scared the absolute life out of myself.

Parents’ worries focus on the future. For example, will there be psychological impact; will it progress to surgery; will it impact on education? Parents described ‘watchful waiting’ as a place of anxiety. They describe the initial shock of the diagnosis.

FATHER: the first X-ray was a big shock . . . she can be quite a joker [but] said ‘my spine is really bent’ . . . and it was. And the doctor said ‘you have actually got two curves and its more severe than I first thought’ . . . he clicked it up on screen and it was a shock to see.

Some parents described a sense of culpability: how did I miss it; is it my fault; why can’t I make it go away?

MOTHER: I had to have a lumbar puncture so I was thinking was it the lumbar puncture? . . . there was a fair bit of guilt . . . the logical side of my brain knows that that is absolute nonsense . . . but there were times when I did torture myself.

FATHER: You want to press a magic button and do . . . but it’s not going to be the case . . . it’s that old cliché isn’t it the only thing you want for your children is good health.

In contrast to their own worry, parents noticed that their daughters seemed to ‘take it in their stride’.

FATHER: Show us to take our cues from the children. Take strength from how children approach it. They have been amazingly laid back. What difference has it made? It has had precious little effect.

The girls (without pain) confirmed that scoliosis was not such a ‘big deal’.

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3 GIRL: Don't worry and just keep calm . . . I feel fine, it doesn't really make any  
4 difference. . . [my parents] probably just worry that I am worried but I'm not. . .  
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6 didn't know what it was at first, I wasn't very happy about it but I wasn't devastated.  
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8 I cope. You just get used to it  
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12 GIRL: I think, I don't think its impact I do think about it, as an improvement but it  
13 hasn't changed how I act or anything like that. . . I always try and do everything I  
14 would be able to do if I didn't have it. Cos I don't want to feel restricted or anything  
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16 . . . I probably go out with my friends like I went bowling the other week with my  
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18 friends go to the cinema and that. . . it doesn't really stop me from getting on with  
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20 things.  
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25 The girls had not noticed their curve prior to their diagnosis of AIS and concerns about body  
26 image were not prevalent.  
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29 GIRL: I think it was in the summer holidays, obviously not this year and not last year  
30 either, it was probably the year before and mum was putting sun cream on me when  
31 she noticed that one shoulder was higher than the other. We didn't think anything  
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33 of it and when we got home we went to the doctor, I can't really remember.  
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38 They talked about AIS as something that was very common in adolescents.  
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40 GIRL: I found out it was a lot more common than I thought, like two of the people at  
41 school, one of my very close friends she found out she had it a few months ago. So  
42 when you have it you realise how common it is. Basically it's quite common when  
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44 you are a teenager when you are growing. I don't know why it happens, I think it's  
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46 when you are kind of growing your body goes a bit weird and obviously your spine  
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48 should be going straight up but your spine might go off a bit. I know it can happen  
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50 in, I don't know if you can be born with it, you can get babies who have it and it can,  
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52 and you can get it any age but it is more common when you are growing.  
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55 Parents worried that their child might not be revealing their true worries.  
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58 MOTHER: Sitting in the waiting room thinking . . . 'oh God that will be her' . . . I've  
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60 never mentioned it to her but I wonder if she's thinking along the same lines.

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The girls described concerns over the possibility of surgery and the impact that this might have in their future as opposed to present concerns about body image.

GIRL: Maybe what will happen in the future, if it will get worse, what will happen then? Maybe something like that . . . Like if you wouldn't be able to do anything . . . it doesn't give me any pain and it doesn't stop me from doing anything I want to do, no kind of cosmetic thing about it. It would be nice if it was more in line but I don't really care that much. It's just a matter if it gets worse in the future and stops me doing stuff that is the only worry.

GIRL: They said that it shouldn't get worse, but there is still that possibility so I worry about that . . . it would probably be the surgery I would worry about, if it got so bad that I would have to have surgery, and then recovery time after that. The pain from that . . . wasn't there at chance that it could paralyse you or something, your spinal cord.

In this context, some girls were thinking about their futures and making important decisions at school, for example subject choices that would take them towards particular careers. For example:

GIRL: I would like to be in the [armed forces] and I was looking it up [on the internet] but you couldn't be in it if your degrees were 20 degrees over. . . I was looking at, I was on the British Army website and I was looking at the medical conditions that if you have them you can't join and then there was a section for spine problems and then it was there.

Within this space for concerns, both girls and parents described the value of finding out what it was like for others families.

FATHER: It would be useful to have quoted word from actual parents who have shared this experience . . . would be heartening . . . to provide some sort of reassurance. For example, 'your child will probably be worrying less about it than you will' . . . recognising yourself in the situation.

GIRL: I guess it would be kind of interesting, also a good thing to be able to find out if you have something in common for people with a similar thing. I don't know many people with the same condition, sometimes I feel a bit lonely.

Girl: I think some experiences of young people who have it would be useful. Maybe a bit about knowing that other people have it as well and yet they probably have the same worries about it as you have and a kind of thing about people who are worried about the surgery or it is stopping them doing stuff or cosmetic reasons so that they get a sense other people are going through the same things.

### Talk to *HER* as a person

Finally, children and their parents describe the value of a positive experience of healthcare. Families appreciated it when clinicians engaged with their daughter, rather than attending to the parent. For parents, negative experiences focused around a 'cursory attitude'. Parents emphasised the need for a holistic approach and good communication, particularly with children. They described the negative experience of feeling de-compartmentalised; for example, 'I have done my bit' and now it's not my problem.

FATHER: [the doctor] was very cursory. . . as a child you want somebody interested in you rather than only being worried about the angles, saying 'don't worry about it everything is fine, off you go'.

For the children, 'bad experiences' also included frustration about being dismissed if treatment was not indicated, or not knowing what was going to happen next. For example, what happens if my curve is not 'bad enough'?

GIRL: My GP told me I would need surgery or a back brace, so I had prepared myself . . . and then I got told I didn't need it as it wasn't *bad enough* . . . he didn't tell me what options I had to help it, he just said, I don't need surgery I don't need a back brace . . . that was it.

Parents and children also described issues related to privacy. For example: undressing; being talked about; being asked questions about their bodies.



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FATHER: [that surgeon] was brilliant because he gave a gown and left the room. [The other] just said to her ‘take your top off’ . . . she is 16 and I’m her Dad and that wasn’t good . . . when you have seen a couple of thousand people over the years you maybe lose sight of that. . . well we need to think about this for a moment.

**Discussion**

Our findings highlight issues relevant to: (1) the conduct of trials and acceptability of the trial intervention; (2) the valued outcomes and trial outcomes; (3) the experience of the disease condition. These findings resonate with those found by O’Caithan and colleagues in a systematic review of qualitative research in trials (O’Cathain et al., 2013; O’Cathain et al., 2014). Although context specific, our findings highlight specific and generic issues that may be transferable beyond this setting. We do not know why none of the five boys in the exercise arm agreed to be interviewed. Our systematic review indicates that there is no study that explores boys’ experience of AIS and this would be a very useful and interesting line of enquiry for future research. We did not interview patients in the non-exercise group and this may have also been useful in contextualising findings. However our main focus was on exploring the acceptability of the exercise intervention. Finally, we were surprised that the girls did not reveal concerns about body image. This may be because their main concerns were related to fear of surgery and uncertainty about the future. It may also be because the girls had a mild deformity. Fran Toyé did not ask the girls about personal relationships as she felt this beyond the trial parameters, and this line of enquiry may have highlighted concerns about body image. Further research to explore the experience of adolescents with greater curves might also reveal other concerns.

Using an exemplar of qualitative research in a trial feasibility study, we illustrate three potential facets of qualitative research alongside trials (figure 3): (1) Firstly, qualitative research can make a valuable contribution to the trial design by making specific recommendations. (2) Next, it can generate questions which allow trial researchers to contextualise or reflect on trial design and quantitative findings. (3) Finally, qualitative research findings can go beyond the clinical trial in which they are embedded to explore the experience of disease condition and the healthcare provided. Although these three facets overlap, it would be useful for researchers to consider these when proposing and reporting qualitative research in alongside trials.

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3 Firstly, our qualitative research findings allow us to make specific recommendations for a  
4 future trial. For example, one recommendation would be to ensure that sites  
5 recruiting to a main trial are able to offer flexibility of appointment times that fit around the  
6 school day. A second recommendation would be to re-frame the control intervention more  
7 positively. Control interventions are often neglected when it comes to clinical trials but they  
8 are as important as the experimental intervention. A future trial could provide a more  
9 structured framework for the physiotherapists to work from including specific advice about  
10 AIS along with more general advice about current recommendations for exercise for this age  
11 group. The advantages here are two fold – it would provide the physiotherapists with more  
12 structure to deliver the control intervention potentially increasing their confidence in the  
13 control intervention and it would be more appealing to potential participants. This would  
14 make the control intervention more *active* and in essence, result in the comparison of two  
15 active interventions. This approach has been taken in a prostate cancer trial where ‘watchful  
16 waiting’ was reframed as ‘active monitoring’ following a very low level of recruitment  
17 (Donovan, 2012). Similarly, Donovan and colleagues found that participants *and* trial  
18 recruiters demonstrated preferences for a particular treatment. Recruiters were  
19 subsequently asked to present treatments to patients in a different order and to frame the  
20 control ‘watchful wait’ arm as ‘active monitoring’.

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37 Our findings highlighted the need to help trial recruiters and treating clinicians to adopt a  
38 position of *clinical equipoise*. Equipoise is integral to conducting a high quality trial and  
39 refers to the attitude of everyone involved in the study in regard to their beliefs about the  
40 interventions being tested. If people involved in the study do not accept there is genuine  
41 uncertainty around the benefits of the interventions being assessed then this can have a  
42 negative impact on the trial in a variety of ways. It can impact on recruitment to the study if  
43 clinicians assisting with recruitment believe their patients may receive an inferior treatment.  
44 It can affect willingness of potential participants to be randomised if clinicians infer that one  
45 treatment is definitely superior to the other. If randomised participants consider one  
46 intervention superior to another then it can affect adherence to the intervention should  
47 they receive the intervention they believe to be inferior. This can potentially cause resentful  
48 demoralisation resulting in greater withdrawals from one arm of the study. If the clinicians  
49 delivering interventions have strong preferences for one intervention over the other than  
50 this can impact on the delivery of the trial interventions resulting in contamination of the  
51 interventions delivered (i.e. providing elements of the intervention they perceive as superior  
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when they should not) and diluting the effectiveness of the experimental intervention being studied. This is a serious issue and can threaten the validity of a trial. For example, physiotherapists described how they felt a bit uncomfortable if certain patients were randomly allocated to the non-intervention group. Providing a more structured control intervention may have allowed greater confidence to deliver the control intervention and alleviated this discomfort. This is supported by De Salis and colleagues who showed that trial participants have strong preferences, and that ‘usual care’ can be conceptualised as a rejection (deSalis, Tomlin, Toerien, & Donovan, 2008). The demoralisation felt at being allocated to a non-intervention arm could affect trial recruitment and drop-out, and could also mean that we overestimate positive outcomes from the intervention.

Secondly, qualitative research can generate questions and ideas that can help trial stakeholders to reflect on trial design and findings by allowing them to see things from alternative perspectives. We aimed to explore what participants thought about the outcomes used in the feasibility study (Williams et al., 2015), and to find out whether or not these were a valid reflection of good outcome from the participant’s point of view. Our findings encourage us to carefully reconsider which outcomes are important. They do not provide a definitive answer regarding which specific outcome measures to use in a full trial, but rather reflects on important outcome domains. This supports a dialectic and constructed version of knowledge. Indeed, if anything, findings raise *more* questions about *whom*, and *how*, we should decide what a good outcome is. For example, although Cobb angle is the most commonly measured outcome in trials of non-surgical treatments for AIS (Romano et al., 2012), our findings suggest that, up to a point, it is not necessarily the most important outcome domain for patients, families or clinicians. Children and parents placed value on conscious postural awareness and control, raising the question: if my Cobb Angle has not changed (or even got worse) but I can control my posture, is this still a good outcome? Beyond this, are we concerned with conscious, unconscious, static or dynamic postural changes? Our findings also suggest that pain control is a valued outcome for families and should be considered seriously, even if there is no reported association between pain and scoliosis (Minghelli, Oliveira, & Nunes, 2014). We know that up to 47% of teenagers report back pain (Minghelli et al., 2014), and some attribute this pain to AIS. Participants also valued achieving a sense of control over their condition and a future trial might consider including a measure of self-efficacy. This is supported by studies showing that higher levels of self-efficacy is key to successful self-management (de Silva, 2011).

Waiting passively for an unknown outcome was a place of anxiety and as most adolescent with AIS are managed conservatively, this could be a very long and uncomfortable wait.

Finally, qualitative research findings can uncover issues related to disease experience and quality of care that are not directly related to the trial. Indeed, attempts to retain the qualitative research effort within trial parameters do not necessarily sit comfortably with an inductive epistemology. Rather, revealing ideas that were beyond the original scope may indicate rigorous methodology whereby the researcher has challenged their a priori views. However, this does not mean that qualitative research embedded in a trial can take the place of primary qualitative studies designed to focus on the experience of a particular condition. Rather, it might raise issues that would benefit from further qualitative exploration. For example, no boys agreed to be interviewed study and there may be gendered differences in the experience of AIS which future research should consider. In addition, what is the experience from the point of view of other clinicians such as surgeons? Although useful, by singularly focusing on questions pertaining to trial design, conduct and outcomes, rather than global issues, such as disease experience and quality of care, we may not be utilising qualitative research to its full advantage. O’Caithan and colleagues recognise this limitation in their systematic review of studies that ‘enhanced the trial endeavour rather than made an independent contribution to knowledge’ (3).

Our findings highlight two themes relate to the experience of AIS and quality of care: Firstly, unmet information needs and the importance of creating a separate space for parents and children to air their individual concerns; and secondly, the importance of being regarded as a unique individual embedded within a family, as opposed to *‘just a body’* with AIS. This embodied approach to healthcare seeks the human aspects of patients’ experience, as opposed to a dualistic approach which focuses on pathology, diagnosis and cure (Annandale, 1998; Helman, 2007; Lupton, 1994). This resonates with findings from other studies exploring the experience of AIS where patients did not always feel supported by their health care professionals (Sapountzi-Krepia et al., 2006). Rullander and colleagues also support the profound emotional effects that can accompany AIS (Rullander et al., 2013). The innovation of our findings is to demonstrate that a holistic approach should include the family, particularly parents, who may have different information needs and concerns.

We aimed to explore the benefits of including qualitative research within trial design and reflect on some of the epistemological challenges. The *epistemological* differences between qualitative research and trial methodology can make it difficult to evaluate the purpose and utility of qualitative findings in trials, and this creates a danger that qualitative research remains undervalued and unpublished (Greenhalgh, 2016). O'Cathain and colleagues argue that researchers may not be maximising the value of qualitative research undertaken alongside trials. We agree that there are great benefits in planning the qualitative research 'to take a challenging role and develop a learning environment around the use of qualitative research' (O'Cathain et al., 2013; O'Cathain et al., 2014). However, there is also the danger that we set the expectations for qualitative research embedded in trials too high. In short, we need to ensure that trial researchers are not "looking for an awful lot of bangs for their buck" (Munro & Bloor, 2010). Munro and colleagues suggest that more selective sampling in respect of the more labour-intensive qualitative data collection and analysis.

There are some important differences to consider: qualitative research does not aim to generate factual truths, but to encourage us to think (Toye & Jenkins, 2015); it is underpinned by an inductive epistemology that is likely to mean that findings go beyond specific aims stipulated in a trial protocol. Therefore judging the quality of qualitative research by whether or not the aims were met might not necessarily be useful. Beyond the trial setting, qualitative research alongside in trials can also help us to think about what it is like to be a person with a particular condition. A person's experience of healthcare is integral to positive health outcomes and as such should be considered in the design of interventions and research.

To make the most out of qualitative research alongside quantitative research designs it would be useful to: (1) agree specific qualitative study aims that underpin specific research designs; (2) understand the impact of differences in epistemological truth claims; (3) provide clear thematic interpretations for trial researchers to utilize; (4) Include qualitative findings that explore experience beyond the trial setting within the study impact plan. Our findings illustrate how qualitative research can make a valuable contribution to trial design not only by making specific recommendations, but also by allowing trial stakeholders to see things from alternative perspectives. Qualitative research findings can go beyond the clinical trial in which they are embedded and make an independent contribution to knowledge.

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**Figure 1 Example search syntax - MEDLINE**

Qualitative MESH and free text terms	Combined with (AND)
exp QUALITATIVE RESEARCH exp INTERVIEWS AS TOPIC exp FOCUS GROUPS. NURSING METHODOLOGY RESEARCH ATTITUDE TO HEALTH Qualitative ADJ5 (theor* OR study OR studies OR research OR analysis) (emic OR etic).ti,ab phenomenolog*.ti,ab hermeneutic*.ti,ab heidegger* OR husserl* OR colaizzi* OR giorgi* OR glaser OR strauss OR (van AND kaam*) OR (van AND manen) OR ricoeur OR spiegelberg* OR merleau constant ADJ3 compar* focus ADJ3 group* grounded ADJ3 (theor* OR study OR studies OR research OR analysis) narrative ADJ3 analysis action ADJ research (digital ADJ record) OR audiorecord* OR taperecord* OR videorecord* OR videotap* cooperative AND inquir* OR co AND operative AND inquir* OR co- operative AND inquir* (semi-structured OR semistructured OR unstructured OR structured) ADJ3 interview* (informal OR in-depth OR indepth OR "in depth") ADJ3 interview* (face-to-face" OR "face to face" ) ADJ3 interview* "IPA" OR "interpretive phenomenological analysis" "appreciative inquiry" social AND construct* OR (postmodern* OR post-structural*) OR (post structural* OR poststructural*)OR (post modern*) OR post-modern* OR feminis*) humanistic OR existential OR experiential	exp SCOLIOSIS scoliosis.ti,ab



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Figure 2. Sample interview questions.

**Adolescent/Parent:**

Can you tell me how you first noticed your/her scoliosis/ what happened next?

Can you tell me what you know about scoliosis?

How do you feel about having scoliosis?

Can you talk to me about what you felt like when you found out? How do you feel now?

Can you tell me about what it has been like coming to hospital?

Can you tell me about anything that worries you at all because of your scoliosis?

What did you want to get out of doing the trial?

Can you tell me about the exercises/trial that you have been doing?

Would you change anything about the exercises/trial?

What would you measure if you wanted to test if someone had improved?

Have you noticed any changes at school? friends? Home? Leisure?

Is there anything else that you would like to talk about?

**Physiotherapist:**

What impact do you think having is scoliosis has on the adolescent/family?

Can you tell me anything that the adolescent/families thought about being in the trial?

Did you think that doing these exercises would stop the curves progressing or reverse progression? What do you think now?

What were your expectations of the study met?

What do you think makes it difficult/easy for some children with scoliosis to stick to the exercises?

Did you notice any particular likes/dislikes/problems?

If you were planning an intervention/trial for scoliosis, what would you change?

What do you think about the outcome measures used in this study?

Would you like to talk about anything else?

Figure 3

Facets of value added by qualitative research - an example from a trial feasibility study

